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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/617,038

07/11/2003

Peter Andersen

SS15AUSA

5215

270 7590 08/05/2009  
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EXAMINER

SWARTZ, RODNEY P

ART UNIT

PAPER NUMBER

1645

NOTIFICATION DATE

DELIVERY MODE

08/05/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@howsonandhowson.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/617,038	<b>Applicant(s)</b> ANDERSEN ET AL.	
	<b>Examiner</b> Rodney P. Swartz, Ph.D.	<b>Art Unit</b> 1645	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 May 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 9,10,12,13,16,17 and 24-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9,10,12,13,16,17 and 24-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### **Continued Examination Under 37 CFR 1.114**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7 May 2009 has been entered.

Claims 9, 16, 17, 26 and 29 have been amended. New claims 30-40 have been added.

2. Claims 9, 10, 12, 13, 16, 17 and 24-40 are pending and under consideration.

### **Rejections Withdrawn**

3. The rejection of claims 9, 10, 12, 13, 16, 17, and 24-27 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is withdrawn in light of the amendment of the claims.

4. The rejection of claim 29 under 35 U.S.C. 112, second paragraph, as being indefinite for dependence from a rejected claim, is withdrawn in light of the amendment of the claim.

### **Rejections Maintained**

5. The rejection of claims 12, 13 and 28 under 35 U.S.C. 102(b) as being anticipated by Horwitz (U.S. Pat. No. 5,108,745), is maintained for reasons of record.

Applicants argue that their goal is not to invalidate the cited patent on the basis of inoperativeness or lack of written description, but to establish that the products referenced by Horwitz are secreted products and are in fact very different from the components recited in the present claims.

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The examiner has considered applicants' arguments, in light of the submitted Declarations, but does not find them persuasive for the reasoning put forth in the prior explanations. In addition, the Declaration of Dr. Andersen, page 3, lines 1-8, states that "although the secretion of extracellular proteins is a continual process the composition and relative quantity of proteins in the mixtures of secreted antigens (the so called secretome) is very different when comparing exponentially growing and dormant/non-replicating mycobacteria" and "Many of the major proteins expressed extracellularly during the exponential growth phase are absent or downregulated during the latent/dormant phase". Dr. Andersen does not state that "all" are absent or downregulated.

The instant claims do not restrict the identity of the polypeptide other than those which are upregulated "or" expressed during the latent stage. There is no recitation of amount of expression. Thus, in light of the statements of Dr. Andersen, the proteins taught by the cited patent remain anticipatory of the claimed compositions.

6. The rejection of claims 9, 10, 12, 13, 16, 17, and 24-27 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is maintained for reasons of record.

Applicants argue that the amendment of the claims to delete "fragments" obviates the rejection.

The examiner has considered applicants' argument in light of the claim amendments, but does not find it persuasive for the reasons put forth in the prior explanations, i.e., while the specification provides vaccine examples of whole BCG, ESAT6, Rv2031c, and Rv0569, and two fragments of Rv2031c. The specification does not teach any vaccines comprising polypeptides of the other sequences listed in SEQ ID NOs:1-45.

### **Claim Rejections - 35 USC § 112**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 9, 31 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to vaccines comprising  $\geq 1$  mycobacteria polypeptide fused to "an antigen expressed by bacteria within the mycobacteria family". It is unclear what is the relationship of the polypeptide with the antigen. Can they be the same identical polypeptide or must they be nonidentical?

8. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to a vaccine further comprising "antigen components with prophylactic activity". It is unclear: 1) what is the source of the antigen component, and 2) what is the prophylactic activity against?

9. Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The claim is drawn to a vaccine delivered in a delivery system "such as" an adjuvant. It is unclear what metes and bounds are placed on the delivery system because the phrase "such as" does not define the scope of the term.

10. Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to the vaccine according to claim 29, "wherein the one or more polypeptides has an amino acid sequence of SEQ ID NO:24". Claim 29 recites that the one or more polypeptides has an amino acid sequence selected from SEQ ID NOs 1-45. It is unclear in those embodiments of claim 30 which are drawn to more than one sequence listed in claim 29 how each sequence has SEQ ID NO:24.

11. Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is an improper Markush grouping because the group does not end with "and" or "or".

12. Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrasing of the claim is unclear, i.e., "further comprising the antigen components with prophylactic activity are selected".

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13. Claim 38 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites "peptides" as components in lines 2 and 3, but recites "polypeptides" in line 3. If the two words are defining the same moiety, then utilizing "polypeptides" is recommended in order to be consistent with the rest of the claims.

14. Claim 40 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is an improper Markush grouping because the group does not end with "and" or "or".

15. Claims 29-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a therapeutic vaccine comprising  $\geq 1$  polypeptide selected from SEQ ID NOs:1-45.

The specification provides vaccine examples of only whole BCG, ESAT6, Rv2031c, and Rv0569, and two fragments of Rv2031c. The specification does not teach any vaccines comprising the other sequences in the listing of SEQ ID NOs:1-45.

Therefore the claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the

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inventors, at the time the application was filed, had possession of the claimed invention, i.e., vaccines comprising  $\geq 1$  polypeptide selected from SEQ ID NOs:1-45.

16. Claims 10, 17 and 24-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims depend from rejected claims.

### **Conclusion**

17. No claims are allowed.

18. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

August 3, 2009